

Notice of Allowability

Application No.

09/531,969

Examiner

Robert M. Kelly

Applicant(s)

GELIEBTER ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/19/05.
2. ☒ The allowed claim(s) is/are 65-67.
3. ☒ The drawings filed on 21 March 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08)
Paper No./Mail Date pt 2 of 8/20/03, 7/8/2004; 2/2/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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DETAILED ACTION

Applicant's amendments and arguments of 7/19/05 are entered.

Note: Change in Art Unit and SPE

The Examiner has been reassigned to Art Unit 1633. Therefore, future correspondence should reflect such changes. Also, at the end of the Action is the information regarding the SPE of the Art Unit.

Information Disclosure Statement

It is noted that Applicant submitted a second copy of the IDS submitted on 7/8/04, on 2/2/05; however such IDS was not signed. As is noted in Applicant's cosubmitted argument, these references cited are identical to those already indicated as considered (Applicant's argument of 2/2/05, p. 9). Therefore, the IDS of 2/2/05 was not ~~signed~~^{considered}, because such would put two copies of each reference cited therein onto the face of any patent which issues from this Application. (I.e., such references have already been considered and indicated as considered in the IDS submitted 7/8/04.)

With regard to the IDS of 3/20/03, it is noted that Examiner Paras signed and initialed the first page of the two pages of IDS supplied by Applicant (signed copy sent to Applicant on 8/13/03). Herein is enclosed a copy of page 2 of the two pages, which is signed and has been considered by the present Examiner.

Consideration of U.S. Patent No. 6,271,211

U.S. Patent No. 6,271,211 (Issued from Application No. 09/532,138) was considered with respect to obviousness-type double patenting. The issued patent comprises a method of treating penile flaccidity caused by heightened contractility of the penile smooth muscle in a subject, comprising administration of a DNA encoding the K-ATP Kir6.2 subunit, to result in less heightened contractility of the penile smooth muscle in the subject.

However, as provided in the Official Action of 2/21/02, the art was unpredictable at the time of invention. Hence, if any particular potassium channel protein was shown to be functional in the methods, such would not make obvious any other potassium channel in the same method, and therefore, U.S. Patent No. 6,271,211 is not an obviousness-type ODP with the present claims.

Improper Citation in the Notice of References Cited of 6/6/01

Examiner Paras cited an article by Eck, et al., entitled "Scope of Gene Therapy", in the PTO-892 form of 6/6/01. Such citation is improper, lacking a date of such publication. The proper citation is Eck, et al. (1996) Goodman & Gilman's The Pharmacological Basis of Therapeutics, 9th Ed., McGraw-Hill, New York, NY., pp. 77-101, entitled "Gene-Based Therapy".

Claim Status, Cancelled Claims

In light of Applicant's cancellation of claims 50, 54-56, and 59-64, all rejections and/or objections to such claims are rendered moot, and thus are withdrawn.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

IN THE TITLE:

1. The title has been rewritten as follows:

A method of enhancing relaxation of penile smooth muscle by introduction of DNA encoding maxi-K potassium channel protein.

IN THE SPECIFICATION:

2. The first paragraph of the specification, beginning on the fourth line of page 1 of the specification has been rewritten as follows:

This is a continuation-in-part of copending U.S. Application No. 08/799,144, filed February 13, 1997, and issued as U.S. Patent No. 6,150,338 on November 21, 2000, and a continuation-in-part of copending U.S. Application No. 09/135,849, filed August 18, 1998, now abandoned, both of which are hereby incorporated by reference in their entireties.

The following is an examiner's statement of reasons for allowance:

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Applicant has overcome the written description and enablement rejections previously presented, by limiting the potassium channel to the maxi-K potassium channel. It is noted that Applicant has limited the scope of the claims to come within the scope previously found enabled and to have written description.

Also, the Art does not teach or suggest the use of such protein encoded in a DNA for relaxation of such penile smooth muscle.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 65-67 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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